



ReNeuron Limited

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The Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852
USA

30 November, 1999

Dear Sir or Madam,

Re: Comments to Proposal on Donor Suitability and Donor Testing Proposal:
Published in the Federal Register, Vol 64, Vol 64 No 189 on Thursday
September 30 1999. **Docket Number 97N-484S.**

I am writing in reference to the above proposed regulation as the CEO of a research phase biotechnology company aiming to develop clonal lines of human, neural, stem cells derived from fetal material donated at termination of pregnancy.

In making this comment to the proposal it is important to appreciate that neural cell lines would not be first implanted for at least 9 months and perhaps one and a half years after the original tissue donation – this being the period of time required to develop and test for efficacy and safety the clonal line. Each cell line would subsequently be used to treat many patients suffering from neurological diseases.

While acknowledging the importance of initial donor screening and testing (as defined in proposed 1271.50) we believe that the requirement for re-testing the donor at 6 months after donation (proposed 1271.80) is both unnecessary and impractical for the type of product we are seeking to develop. It is unnecessary since the cells themselves can be reliably and sensitively tested by modern molecular biology techniques for the agents specified in proposed 1271.85. Cells can be tested both when preparing master cell banks and when releasing final product. We also believe that it is impractical and insensitive to request re-testing of the woman and will in our opinion decrease the willingness of women to donate and prolong the trauma associated with a termination of pregnancy .

Registered Office: 67168 Jermyn Street, London SW 1 Y 6NY

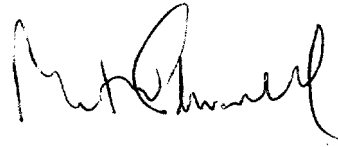
Registered Number: 3375897

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We appreciate the opportunity provided by the FDA to comment upon these proposals.

Sincerely,

A handwritten signature in black ink, appearing to read "Martin Edwards". The signature is fluid and cursive, with a large initial "M" and a long, sweeping underline.

Martin Edwards MD


BY AIR MAIL
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